

DETAILED ACTION

Claims 1-10, 14 and 15 are under consideration in this application.

Claims 11-13 remain held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.141(b).

Election/Restrictions

The restriction requirement is deemed sound and proper and is hereby made FINAL.

Again, this application has been examined to the extent readable on the elected compound wherein, het is a pyrazole in claim 1, exclusively.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The expression "pyrazole.....substituted in the...linkage" is employed with considerable abandon in claim 1 with no indication given as to what substituents really are.

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Applicants merely assert that the claim has never mentioned pyrazole, per se. Only the **pyrazoles** are under examination herein. Applicants have failed to recite the substituents on the pyrazole.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. Applicants are referred to In re Fouche, 169 USPQ 429 CCPA 1971, MPEP 716.02(b).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention

The nature of the invention is the preparation of the claimed compounds.

State of the Prior Art

Substituents can have very different properties. Substituents tend to convert from less stable to more stable forms. No method exists to predict what group will work with any significant certainty.

The amount of direction or guidance and the presence or absence of working examples

The specification fails to describe any substituents. Substituents often change into other forms during manufacture. Based on the unpredictability in the art, applicants are not entitled to any and all unknown substituents.

The written description is considered inadequate here in the specification. Conception of the intended substituents and complexes should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. *In re Kirk*, 153 USPQ 48, at page 53.

The breadth of the claims

The breadth of the claims are drawn to all substituents in addition to the instant unsubstituted compounds.

The quantity of experimentation needed

The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the compounds and their unknown other forms being claimed.

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In terms of the 8 Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of unpredictability in the art of the invention, and the poor amount of direction provided by applicants. Taking the above factors into consideration, it is not seen where the instant other forms are enabled by the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression “pyrazole... substituted in the position”. Claim 1 fails to recite what the substituents are.

Again, the plural ‘s’ on “salts” makes claim 1 read on mixtures rather than specific compounds.

Contra to applicants’ arguments in the instant response, one cannot tell from a simple reading of the claim what is being claimed. One must first conceive of the salt. Then one must, by preparing the compound himself, determine if the salt works or not. Where is the specific claiming and distinctly pointing out? How can applicants regard as their invention inexact concepts? The breadth of which they could not have possibly checked out with representative exemplification. The term is not finite.

Applicants are claiming a compound of the formula. Pure chemistry, a compound. Not a resin of general property ranges, but a pure compound. That compound used for any purpose is taken from the public in a 20-year monopoly to applicants. Then, the

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public is entitled to know what compound they cannot use. Yet, the claim is not specific to that compound. The public cannot tell what they may not use. How is a claim of the instant breadth defensible in an infringement action?

As applied to pure compounds, *In re Cavallito and Gray*, 134 USPQ 370, and *In re Sus and Schaefer*, 134 USPQ 301, are considered to set the proper applicable standard of required definiteness and support.

The claims measure the invention. *United Carbon Co. v. Binney & Smith*, 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in *Lockheed Aircraft Corp. v. United States*, 193 USPQ 449, "Claims measure invention and resolution of invention must be based on what is claimed".

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": *In re Priest*, 199 USPQ 11, at 15.

Terminal Disclaimer

The terminal disclaimer filed on September 21, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Ser. no. 12/292,676 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

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Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and if rewritten directed solely to the elected compounds.

Claims 2-10, 14 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if rewritten directed solely to the elected compounds.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Patricia L. Morris/
Primary Examiner, Art Unit 1625

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November 9, 2009